SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Subpart B—Quality Standards and Certification

AUTHORITY: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

EFFECTIVE DATE NOTE: At 62 FR 55976, Oct. 28, 1997, part 900 was revised; and at 62 FR 60614, Nov. 10, 1997, it was republished and corrected, effective Apr. 28, 1999, with excepted provisions effective Oct. 28, 2002. For the convenience of the user, revised and corrected part 900 follows the text of this part.

Subpart A—Accreditation

SOURCE: 58 FR 67562, Dec. 21, 1993, unless otherwise noted.

§900.1 Scope.

The regulations set forth in this part implement 42 U.S.C. 263b(b) through (f). The intent of subpart A of this part is to establish application procedures for accrediting bodies and to establish requirements and standards for such bodies to ensure that all mammography facilities in the United States are adequately and consistently evaluated for compliance with quality standards for mammography. The intent of subpart B of this part is to establish procedures for facility certification and to establish quality standards for mammography facilities to assure safe, reliable, and accurate mammography on a nationwide level.

§900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accrediting body* or *body* means an entity that has been approved by FDA under 42 U.S.C. 263b(e)(1)(A) to accredit mammography facilities.

(b) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(c) *Certification* means the state of approval of a facility by FDA to provide screening and diagnostic mammography services.

(d) *Clinical image* means a mammogram.

(e) *Facility* means a hospital, outpatient department, clinic, radiology practice, or mobile unit, office of a physician, or other facility that conducts breast cancer screening mammography activities or conducts diagnostic mammography activities, including the following: The operation of equipment to produce a mammogram, processing of film, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(f) *Interpreting physician* means a physician who interprets mammograms made during screening or diagnostic mammography procedures and who meets the requirements of §900.12(a)(1).

(g) *Mammogram* means a radiographic image produced through mammography.

(h) *Mammography* means radiography of the breast.

(i) *Medical physicist* means a person meeting the qualifications for a medical physicist set forth in §900.12(a)(3).

(j) *Patient* means any individual who undergoes clinical evaluation in a mammography facility, regardless of whether the person is referred by a physician or is self-referred.

(k) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and

containing components that radiographically model aspects of breast disease and cancer.

(l) *Phantom image* means a radiographic image of a phantom.

(m) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

(n) *Radiographic equipment* means x-ray equipment used for the production of static x-ray images.

(o) *Radiological technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in § 900.12(a)(2).

(p) *Qualified practicing physician* means a physician meeting the requirements of an interpreting physician as specified under § 900.12(a)(1).

(q) *Survey* means an on-site physics consultation and evaluation of a facility performed by a medical physicist.

(r) *Diagnostic mammography* means mammography performed on a patient with: clinical signs, symptoms, physical findings suggestive of breast cancer; an abnormal or questionable screening mammogram; a history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms, or physical findings; or, augmented breasts regardless of absence of clinical breast signs, symptoms, or physical findings. Diagnostic mammography is also called problem-solving mammography or consultative mammography. This definition excludes mammography performed during invasive interventions for localization or biopsy procedures. The definition further excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(s) *Screening mammography* means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage. This definition excludes mammography performed as part of a scientific study to evaluate an experimental mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

[58 FR 67562, Dec. 21, 1993; 59 FR 6899, Feb. 14, 1994, as amended at 59 FR 49812, Sept. 30, 1994]

§ 900.3 Application for approval as an accrediting body.

(a) *Eligibility*. Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accrediting bodies.

(b) *Application*. One copy of an application for approval as an accrediting body shall be submitted to the Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and should be marked ATTENTION: Mammography Program. Applications for approval as an accrediting body should include the following information:

(1) Name, address, and phone number of body and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the body is not a State agency;

(2) Standards the body agrees to impose on facilities pursuant to 42 U.S.C. 263b(e)(3);

(3) Methods for performing clinical image review as required in 42 U.S.C. 263b(e)(1)(B)(i)(I);

(4) Methods for monitoring and evaluation of annual surveys of facilities by medical physicists as required in 42 U.S.C. 263b(e)(1)(B)(v);

(5) Methods for performing on-site inspections of facilities as required in 42 U.S.C. 263b(e)(4);

(6) Fee schedules, with supporting cost data; and

(7) Satisfactory assurances that the body will comply with the requirements of § 900.4.

(c) *Ruling on application*. FDA will approve an accrediting body if FDA determines upon review of the application that the body substantially meets (or will substantially meet when it begins to evaluate facilities) the requirements of this subpart, and the body's standards are substantially the same as the quality standards published